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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/357,709	07/20/1999	NEIL H. BANDER	242/026	9637

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/26/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/357,709

Applicant(s)

BANDER, NEIL H.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-77,79-81,84-95,107,115-128 and 130-152 is/are pending in the application.
- 4a) Of the above claim(s) 133-142 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 68-77,79-81,84,86,88,90,92,94,107,111,112,114,116-128 and 130-132 is/are allowed.
- 6) ☒ Claim(s) 85,87,89,91,93,95,113,115 and 143-152 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

The Amendment filed June 23, 2003 (Paper No. 24) in response to the Office Action of January 22, 2003 is acknowledged and has been entered.

Claims 78, 108-110, and 129 were cancelled.

Claims 133-152 were added.

Claims 133-142 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 68-77, 79-81, 84-95, 107, 115-128, 130-132, and 143-152 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

NEW OBJECTIONS/REJECTIONS:

Election/Restrictions

Newly submitted claims 133-142 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The new claims are broadly drawn to detecting benign hyperplasia *in any tissue* which is broader in scope than the

Art Unit: 1642

elected subject broader drawn to detecting normal, benign hyperplastic, or cancerous *prostate* cells.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 133-142 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The specification is objected to on page 42, line 3 for reciting "nucleotide" since the sentence is in reference to an amino acid sequence.

The specification is objected to on page 43, line 33 for reciting "nucleotide" since the sentence is in reference to an amino acid sequence.

The specification is objected to on page 44, line 33 for reciting "nucleotide" since the sentence is in reference to an amino acid sequence.

Claim Objections

Claims 85, 87, 89, 91, 93, and 95 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The objected claims all depend from Claim 84 or 90, Markush-type claims drawn to *discrete* antigen binding portions. However, the objected claims are broader in scope than Claims 84 or 90 because they include different antigen binding portions than those claimed in Claim 84 or 90. For

Art Unit: 1642

example, Claim 85 includes an antigen binding portion of an amino acid sequence of the variable heavy chain produced by hybridoma having ATCC deposit no. HB-12126 *and* an antigen binding portion of an amino acid sequence of SEQ ID NO:19 (variable light chain) *or* an amino acid sequence of the variable light chain produced by the hybridoma having ATCC deposit no. HB-12126. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 85 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are so unclear that no meaningful interpretation can be made as to what exactly the antigen binding portions comprise. For example, Claim 145 includes an antigen binding portion of an amino acid sequence of the variable heavy chain produced by hybridoma having ATCC deposit no. HB-12126 *and* an antigen binding portion of an amino acid sequence of SEQ ID NO:19 (variable light chain) *or* an amino acid sequence of the variable light chain produced by the hybridoma having ATCC deposit no. HB-12126. Are these portions conjugated to one another? Are they separate? What exactly is meant by including the term “and” ? What is meant by including the term “or” ? Hence, the metes and bounds of the claims cannot be determined.

Art Unit: 1642

Claims 143-152 recite the limitation “normal, benign hyperplastic” in Claim 143. Since the preamble of the method claim is solely drawn to detecting “cancerous prostate cells”, there is insufficient antecedent basis for this limitation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 85, 87, 89, 91, 93, 95, 113, 115 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims are broadly interpreted to encompass antigen binding portions that are conjugated, and the specification does not appear to have support for such combinations. For example, Claim 87 is drawn to antibody or antigen binding portion thereof that comprises an antigen binding portion of an amino acid sequence from SEQ ID NO:8 *and* an antigen binding portion of an amino acid sequence from SEQ ID NO:19. However, the specification only supports those antigen binding portions selected from the group consisting of SEQ ID NO:8, SEQ ID NO:19, an amino acid sequence of the variable heavy chain produced by the hybridoma having ATCC deposit No. HB-12126, and an amino acid sequence of the variable light chain produced by the hybridoma having ATCC deposit No. HB-12126.

Art Unit: 1642

Although, the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06 (“Applicant should specifically point out the support for any amendments made to the disclosure.”)

All other rejections and or objections are withdrawn in view of applicant’s amendments and arguments there to.

Claims 68-77, 79-81, 84, 86, 88, 90, 92, 94, 107, 111-112, 114, 116-128, 130-132 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/357,709

Page 7

Art Unit: 1642

Gary B. Nickol, Ph.D.

Examiner

Art Unit 1642

GBN

August 21, 2003

A handwritten signature in cursive script, appearing to read "Gary B. Nickol".